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Safety and feasibility of unsedated peroral percutaneous endoscopic gastrostomy placement in both outpatient and inpatient settings

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Abstract

Percutaneous endoscopic gastrostomy (PEG) is traditionally performed under sedation. However, sedation is often associated with cardiopulmonary risks. Unsedated PEG placement may be an alternative in patients with a high anesthesia risk. However, there are only a few studies in the literature on the feasibility of oral unsedated PEG placements. Additionally, there are conflicting results in the literature regarding whether PEG placement increases mortality in hospitalized patients. The primary aim of this study was to investigate the safety and feasibility of peroral PEG placement without sedation in our surgical endoscopy unit. Secondly, we aimed to compare the mortality and morbidity results of unsedated PEG placements in inpatients (IP) and outpatients (OP). The medical records of patients who underwent peroral unsedated PEG placements in our surgical endoscopy unit between September 2019 and September 2022 were reviewed retrospectively. The patients were divided into two groups: inpatients (IP) and outpatients (OP). Demographic data, PEG indications, comorbidities, procedural success rate, PEG-related complications, and 30-day mortality data were analyzed. A total of 312 patients were included in the study, with a median age of 79 years (interquartile range (IQR): 70-86). The overall PEG-related complication rate was 9.2%, and the 30-day mortality rate was 5.1%. The procedure success rate was 99%. There were no statistically significant differences between the groups in terms of PEG indications, PEG-related complications, and mortality (p=0.430, p=0.384, and p=0.437, respectively). This study demonstrates that unsedated PEG placement using the conventional peroral route is a safe and feasible procedure, regardless of the indications. Also, the PEG procedures can be performed safely on outpatients without increasing complications. Furthermore, the study findings suggest that inpatient PEG placement does not lead to increased mortality rates compared to outpatient PEG placement.

Keywords: percutaneous endoscopic gastrostomy, unsedated, peroral, inpatient, outpatient, mortality

1. Introduction

Percutaneous endoscopic gastrostomy (PEG) is a leading long-term enteral nutrition (EN) technique used for patients who require nutritional support due to inadequate oral intake and swallowing disorders, provided they have a functional gastrointestinal system(1). It was first reported four decades ago by Gauderer et al. using a regular de Pezzer catheter and has since become increasingly widespread worldwide with the development of commercial kits(2, 3).

PEG tube placement, as a minimally invasive procedure, is traditionally performed under sedation in many centers. Procedural sedation increases patient comfort and enhances the reliability of the technique by facilitating the convenience of the procedure-performing team(4). However, administering IV sedation carries certain risks, including respiratory and circulatory complications(5). These risks should be approached with caution, particularly in patients with respiratory comorbidities, as reports of apneas and severe hypoxia associated with sedation have been documented(6). Consequently, some patients may have their PEG insertion canceled, and alternative feeding methods may be preferred due to the risks associated with sedation. Our understanding of whether PEG can be performed without sedation in such patients is very limited.

When reviewing the literature on PEG placement without sedation, studies primarily utilizing the trans-nasal route and ultrathin endoscopes are encountered(7-9). However, there are only a few studies in the literature that investigate oral, unsedated PEG placements(10-12). Furthermore, the number of patients included in these studies is relatively small. Additionally, conflicting results regarding mortality associated with PEG insertion in outpatients (OP) and inpatients (IP) can be found in the literature. Abuksis et al., in their two different retrospective studies, concluded that PEG placement in inpatients increases mortality and should be avoided(13, 14). Conversely, in a more recent prospective multicenter study, Anderloni et al. demonstrated that mortality rates in PEG-implanted patients were similar between IP and OP groups(15). Therefore, the primary objective of this study was to assess the safety and feasibility of peroral PEG placements in a larger patient cohort with various indications. Secondly, we aimed to

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compare the complications and mortality rates of oral unsedated PEG placements in IP and OP settings.

2. Materials and Methods

A retrospective review was conducted on patients referred to our surgical endoscopy unit for PEG placement between September 2019 and September 2022. Data were obtained from our hospital database after receiving approval from the local ethics committee (IRB Approval Number: 2021/6/3). Adult patients who underwent PEG implantation using the conventional per-oral method without sedation for any indication were included in the study. Patients who were currently hospitalized in the intensive care unit (ICU), intubated, and undergoing sedation or general anesthesia were excluded. The patients were divided into two groups: inpatients (IP) and outpatients (OP). Demographic characteristics such as age, gender, and comorbidity status, as well as PEG indications, complications, and 30-day mortality data, were recorded.

2.1. PEG procedure

After a minimum 8-hour fasting period, all patients were taken to the endoscopy room. Prior to the procedure, their blood pressure, pulse, and oxygen saturation (SpO2) were monitored. Oxygen support was provided to all patients via a nasal cannula at a rate of 3-4 liters per minute. The procedure was performed by an experienced endoscopist surgeon specializing in esophagogastroduodenoscopy (EGD), with the assistance of an endoscopy nurse.

A 9.4 mm gastroscopy device (Fujinon® EG-530 WR, Japan) was used for EGD. The procedure was conducted with the patient positioned in the traditional supine position, following the administration of pharyngeal anesthesia using a 1% lidocaine mucosal pump spray. Eligible patients underwent a basic diagnostic EGD prior to the continuation of the procedure. PEG implantation was then performed using Ponsky's standard "pull" technique in all patients (2). The same standard 20-Fr PEG kit (ZKSK® Technology Co. Ltd. Beijing, China) was utilized for all patients. Cardiopulmonary (CP) adverse events such as oxygen desaturation, hypertension, and bradycardia were recorded by the assisting nurse, and immediate regulatory interventions were made when necessary. Oxygen desaturation was defined as SpO2 levels below 90%. Hypertension referred to systolic/diastolic blood pressures above 180mmHg/100mmHg, respectively. Bradycardia was defined as a heart rate below 50 beats per minute (bpm).

2.2. Post-procedure follow-up

After the PEG placement, the patients were monitored in the endoscopy room for a duration of 30 minutes. Subsequently, outpatients were discharged to their homes or rehabilitation centers, while inpatients were returned to their respective wards. All patients were assessed by nutrition nurses within 4 to 6 hours after the procedure and initiated feeding through the PEG tube at this time. Patients and/or caregivers were provided with information regarding the use of PEG and potential complications (such as peristomal infection, bleeding, abdominal pain, accidental tube dislocation, obstruction, etc.). In the event of complications or any adverse events, patients were encouraged to contact us, and necessary follow-up and treatments were provided. Post-procedure complications and mortality were also recorded for a 30-day period.

2.3. Statistics

Data analysis was performed using IBM SPSS Statistics Version 26. Categorical data were presented as numbers (%), while quantitative data were expressed as median with interquartile range (IQR), represented as the 25th-75th percentile. Fisher's exact test or chi-square test was utilized for comparing categorical outcomes, while the Mann-Whitney U test was employed for continuous variables. A p-value of 0.05 was considered statistically significant.

3. Results

Between September 2019 and September 2022, a consecutive series of 327 patients were referred to our surgical endoscopy unit for PEG placement. Among them, twelve patients were excluded from the study due to their current intubation and sedation in the ICU. A total of 315 PEG attempts were performed without sedation, with 312 of them (99%) successfully completed. Among the three failed procedures, two patients had undergone previous subtotal gastrectomy, making transillumination impossible due to a small remnant gastric pouch. In the remaining patient, complete esophageal blockage prevented the passage of the scope. Ultimately, 312 patients were included and analyzed. The flowchart illustrating the inclusion and exclusion of patients is presented in Fig. 1.

The median age (IQR) of the 312 patients was 79 (70-86) years. Among them, 124 (39.7%) were males and 188 (60.3%) were females. Fifty-nine percent of the patients (185) were outpatients, and forty-one percent (127) were inpatients. The median age of patients in both groups was similar (p=0.404). Hypertension was the most prevalent comorbid condition in both groups (71.7% and 68.9%, respectively). Cerebrovascular accident (40%) and dementia (38.8%) were the top two leading causes for PEG placement. The proportion of patients with a history of previous abdominal surgery was 10.2% in inpatients and 4.3% in outpatients, with no significant difference (p=0.069). The proportion of patients requiring PEG replacement in both groups was comparable (15.7% vs 23.8%, p=0.084). Median levels of total protein and albumin measured before the procedure were significantly lower in the inpatient group (both p<0.005). Table 1 displays the baseline demographic characteristics of the patients.

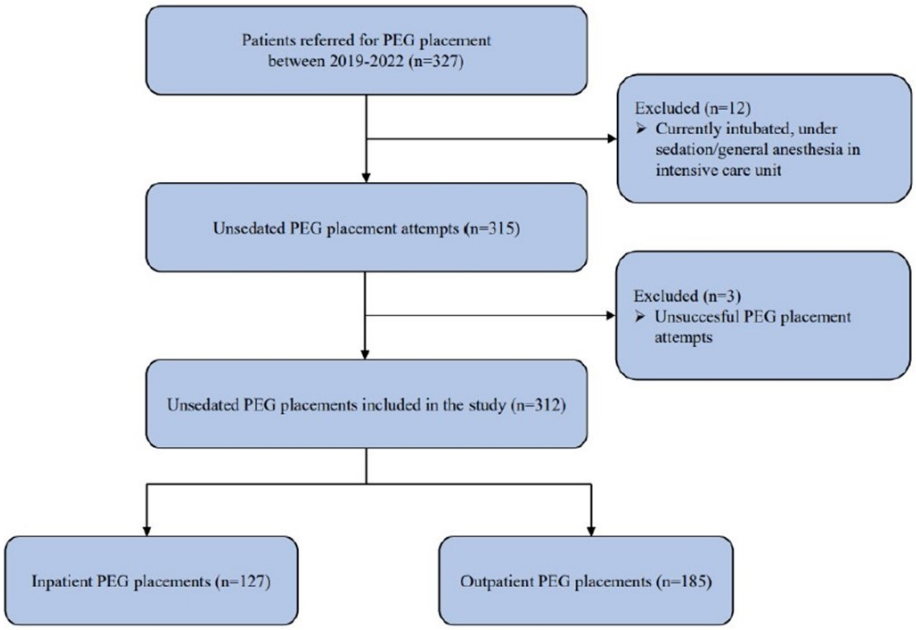

Fig. 1. Study flow diagram. PEG; percutaneous endoscopic gastrostomy

Table 1. Baseline demographic and clinic characteristics of patients in study groups

	Inpatient PEG (n=127)	Outpatient PEG (n=185)	Total (n=312)	P value
Age (years), median (IQR)	78 (70-85)	80 (69-86)	79 (70-86)	0.404
Age				
<65y	22 (17.3)	39 (21.1)	61 (19.6)	0.411
>65y	105 (82.7)	146 (78,9)	251 (80.4)	
Sex				
Male	59 (46.5)	65 (35.1)	124 (39.7)	**0.045**
Female	68 (53.5)	120 (64,9)	188 (60.3)	
Co-morbidity				
Diabetes Mellitus	30 (23.6)	35 (18.9)	65 (20.8)	0.315
Hypertension	91 (71.7)	127 (68.9)	218 (69.8)	0.570
Heart Failure	16 (12.6)	18 (9.7)	34 (10.9)	0.424
COPD	11 (8.7)	16 (8.6)	27 (8.6)	0.997
PEG Indications				0.430
Cerebrovascular accident	48 (37.8)	77 (41.6)	125 (40)	
Dementia	47 (37)	74 (40)	121 (38.8)	
Other neurological disorders	15 (11.8)	21 (11.4)	36 (11.5)	
Oropharynx/esophageal cancers	3 (2.4)	8 (4.3)	11 (3.5)	
Others	14 (11)	5 (2.7)	19 (6.1)	
Previous abdominal surgery	13 (10.2)	8 (4.3)	21 (6.7)	0.069
PEG replacement	20 (15.7)	44 (23.8)	64 (20.5)	0.084
Total protein (g/dl), median (IQR)	5.5 (5.1-6.1)	6.1(5.8-6.8)	6.1 (5.3-6.4)	**<0.05**
Albumin (g/dl), median (IQR)	2.4 (2.1-3.1)	3.1 (2.5-3.3)	2.9 (2.3-3.1)	**<0.05**

Data are presented as n (%) or median (IQR). PEG; percutaneous endoscopic gastrostomy, COPD; chronic obstructive pulmonary disease. Cerebrovascular accident includes ischemic and hemorrhagic stroke patients. Other neurological disorders include amyotrophic lateral sclerosis, Parkinson's disease, and multiple sclerosis. Others include primary lung cancers, brain tumors and metastatic tumors. Bold style indicates statistical significance.

Table 2 shows the distribution of all complications and 30-day mortality data by groups in the study. During the procedure, at least one cardiopulmonary (CP) adverse event developed in 25 patients (8%). Of these patients, 11 were in the inpatient group, and 14 were in the outpatient group, with no significant difference observed in terms of CP adverse events (p=0.727). The number of patients who experienced oxygen desaturation was 9 (7.1%) in the inpatient group and 8 (4.3%) in the outpatient group, and hypoxia was restored by increasing the nasal oxygen flow rate to 10 liters per minute. A total of 5 patients had hypertensive measurements during the procedure, and their blood pressure returned to normal without the need

for additional medication. Patients who developed bradycardia had their heart rate return to normal at the end of the procedure. No severe complications, such as asystole or prolonged apnea, were detected in any patient.

Overall, 29 patients (9.2%) experienced PEG-related complications, and all these complications were classified as minor, with no significant difference between the groups (p=0.384). The most common complication in both groups was peristomal infection, which occurred in a total of 17 patients. These infections were treated with appropriate antibiotics and dressings. Among the patients who experienced abdominal pain after the procedure, pneumoperitoneum was detected in the radiographs and CT scans of 6 patients, but they were monitored without requiring any additional intervention. In two hospitalized patients, the PEG tube was accidentally dislodged but was successfully reinserted. No procedure-related deaths occurred during the study; however, a total of 16 patients (5.1%) passed away within 30 days due to their underlying diseases. Among these deaths, 8 (6.3%) occurred in the inpatient group and 8 (4.3%) in the outpatient group. The 30-day mortality rate did not significantly differ between the two groups (p=0.437).

Table 2. Distribution of complications and 30-day mortality data by groups

	Inpatient PEG (n=127)	Outpatient PEG (n=185)	Total (n=312)	P value
Cardiopulmonary adverse events	11 (8.7)	14 (7.6)	25 (8.0)	0.727
Oxygen desaturation	9 (7.1)	8 (4.3)	17 (5.4)	
Hypertension	1 (0.8)	4 (2.2)	5 (1.6)	
Bradycardia	2 (1.6)	2 (1.1)	4 (1.3)	
PEG related complications	14 (11)	15 (8.1)	29 (9.2)	0.384
Peristomal infection	9 (7.1)	8 (4.3)	17 (5.4)	
Pneumoperitoneum	2 (1.6)	4 (2.2)	6 (1.9)	
Peristomal leakage	1 (0.7)	1 (0.5)	2 (0.6)	
Peg tube dislodgement	2 (1.6)	0 (0)	2 (0.6)	
Peristomal bleeding	0 (0)	1 (0.5)	1 (0.3)	
Peg tube blockage	0 (0)	1 (0.5)	1 (0.3)	
Major PEG related complications	None	None	None	N/A
30-day mortality	8 (6.3)	8 (4.3)	16 (5.1)	0.437
Failed attempt	1 (0.7)	2 (1.0)	3 (0.9)	N/A

Data are presented as n (%) or median (IQR). Oxygen desaturation refers to oxygen saturation below 90%. Hypertension defined as a systolic blood pressure greater than 180 mmHg or diastolic blood pressure greate**r** than 100mmHg. Bradycardia defined as a heart rate of less than 50 bpm. N/A; not applicable

4. Discussion

The findings of this retrospective study indicate that the unsedated per-oral percutaneous endoscopic gastrostomy (PEG) procedure can be safely and successfully carried out in patients with diverse indications, utilizing a standard gastroscope and pharyngeal local anesthesia alone. Furthermore, the study revealed that the mortality rate in patients who underwent PEG placement did not increase among inpatients compared to outpatients.

PEG is an enteral nutrition technique that has been utilized for over four decades, known for its simplicity and safety, and characterized by low rates of major complications(16). However, there is no definite recommendation in the literature regarding the application of the procedure under general anesthesia, local anesthesia, or sedation. Clinical guidelines generally state that sedation is required for PEG placement, and sedatives such as midazolam and propofol can be used(17-19). However, ASGE guidelines and many other publications emphasize that sedation increases cardiopulmonary risks in the presence of advanced age and comorbidities(17). For this reason, there is increasing interest in PEG placement without sedation, especially in patients with high anesthesia risks. A retrospective case series study with 10 patients concluded that unsedated per-oral PEG placement is safe and well-tolerated in a carefully selected patient group(11). Similarly, in a retrospective study that included only stroke patients, it was concluded that unsedated oral PEG insertion is safe and feasible(12). However, the number of patients in these studies is relatively low, and only stroke patients were included. In our study, we included 312 consecutive patients referred for PEG placement to our unit over a span of 3 years, including not only stroke patients but also those with dementia, other neurological diseases, brain and spinal cord injuries, oropharyngeal/esophageal cancers, and all other oncological causes. From this perspective, we can conclude from this study that PEG without sedation is applicable in all patient groups regardless of the indication.

Regarding unsedated PEG placements, it can be seen in other studies in the literature that the transnasal route and pediatric endoscopes (ultrathin) are used instead of the oral route and standard adult endoscopes(7-9). In the prospective study of Lin et al., it was concluded that the transnasal route is a safe alternative when transoral endoscopy is not possible(8). The study of Dumotrier et al. stated that the procedure was completed in 21 (91%) of 23 patients who underwent transnasal PEG intervention(7). Similarly, in the study of McCulloch et al., % success rate of 89.5% was achieved in patients who underwent PEG placement via the transnasal unsedated seated position(9). Unlike these studies, our study used the conventional oral route with a standard gastroscope,

and a success rate of 99% was achieved.

In our study, complications were divided into CP adverse events and PEG-related complications. CP adverse events were seen in 25 (8%) patients. These either resolved spontaneously and quickly or only required minor medical treatments. Oxygen desaturation was the most common CP complication in our study, affecting 17 patients (5.4%). Similar rates of hypoxia were reported in the studies by Tsausi et al. (8.5%) and the ProGas study group (4%)(12, 20).

Regarding PEG-related complications, we encountered 29 patients with a rate of 9.2%. All these complications were classified as minor and were simply treated with medications and dressings. The literature reports a wide range of complication rates, varying between 3.6% and 61%(15, 21-24). In a prospective study from Lombardy, the lowest complication rate was found at a total rate of 3.6%, regardless of the type of anesthesia given(15). Larson et al. reported 13% minor complications in their study, which involved the use of different anesthetics(22). The studies by Schneider et al. and Bloomberg et al., which included patients who had PEG implanted only under IV sedation, reported complication rates of 27% and 39%, respectively(21, 23). Lastly, Shangap et al. reported the highest minor complication rate at 61%(24). Considering these findings, we can conclude that the complication rate in our study was at an acceptable level, consistent with other studies in the literature. We believe that the significant difference in complication rates among studies may be attributed to different follow-up periods, study populations, and the number of patients included.

Our study involved a comparison between inpatients and outpatients regarding the outcomes of the PEG procedure. We found comparable results in PEG-related complications between the groups (11% vs. 8.1%, p=0.384). This finding is consistent with the study conducted by Wilhelm et al. (1). Similarly, in another prospective study investigating the safety of outpatient PEG in patients with head and neck cancer, it was concluded that the early complication rates were similar to those reported for hospitalized patients(25). With this finding, we can conclude that outpatient procedures do not increase complications and hospitalization is not absolutely necessary for the procedure.

30-day mortality was one of the other important parameters we examined in our study, and we observed a total PEG-unrelated mortality rate of 5.1%. We did not have any mortality directly caused by the PEG procedure. This result is consistent with many studies in the literature(14, 15, 20, 26, 27). We also compared the mortality data between inpatients and outpatients, and no significant difference was found. In contrast to our results, two different studies published by Abuksis et al. concluded that PEG procedures performed during hospitalization increase mortality and should be avoided(13, 14). However, like our study, there are also studies showing no increase in mortality in hospitalized patients(15, 27). We believe that the conflicting results may be due to differences in the timing of PEG insertion in hospitalized patients and the varying life expectancies of patients who were recommended to undergo PEG placement. In our approach, most of the PEG placements in inpatients were performed just before the patient's discharge, which may have influenced our results. Another factor that may have affected our mortality data is that intubated and sedated patients in the intensive care unit were not included in this study.

Albumin levels are known to be important prognostic factors affecting mortality and morbidity in many clinical conditions(28). Similarly, low albumin levels have been shown to increase hospital stays and complications in patients with PEG placement(24, 29). Therefore, we measured albumin levels in our study, and the median albumin value was found to be 2.9 g/dl in the total study group. This indicates a hypoalbuminemic state in the patients and highlights the necessity of nutritional support in patients recommended for PEG placement. Additionally, albumin levels were found to be lower in hospitalized patients compared to patients with ambulatory PEG placement.

It should be acknowledged that this study has some limitations. First, due to the retrospective nature of the study, some medical data were lacking and could not be included. Secondly, our study only included 30-day follow-up data. It should be kept in mind that there may be differences in PEG complications and mortality data in longer follow-ups. Third, due to the poor general clinical condition and level of consciousness of the patients, we could not evaluate the procedure comfort scale in the study. Finally, our study only included patients who underwent PEG placement without sedation. Conducting further studies that compare sedated patients and recording the level of tolerance of the PEG procedure by assisting endoscopy nurses may contribute to the literature.

In conclusion, unsedated peroral PEG placement is a safe and feasible procedure regardless of the underlying disease. Our study found no difference in the mortality and morbidity of the PEG procedure between outpatients and inpatients. PEG procedures can be performed safely on outpatients without increasing the risk of complications. Also, PEG insertion can be performed in hospitalized patients with a multidisciplinary approach, using proper patient selection and timing before discharge, without causing an increase in mortality and complications.

Conflict of interest

The authors declare that they have no conflicts of interest.

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The datasets generated and analyzed in this study are available from the corresponding author on reasonable request.

Authors' contributions

Concept: A.B.Ç., Design: A.B.Ç., Data Collection or Processing: K.Y., H.E., Ö.F.B., Analysis or Interpretation: A.B.Ç., Ö.F.B., K.Y., Literature Search: A.B.Ç., Writing: A.B.Ç.

Ethical Statement

Data were obtained from our hospital database after receiving approval from the local ethics committee (IRB Approval Number: 2021/6/3).

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